Translator's general note: The following translation of a German brief will be typed in a nonserif Arial font as in the German text. However, words that appear in English within the German text will be typed in a serif Times Roman font like this.

FEDERAL PATENT COURT
IN THE NAME OF THE PEOPLE
JUDGMENT

4 Ni 33/99 (EU)
joined with
4 Ni 41/99 (EU)
(File No.)

Pronounced on 5 September 2000
Cohnen, Court Employee
as Clerk of the Court's Office

In the patent nullity case

1) of Inflow Dynamics AG, Frankfurter Ring 193a, 80807 Munich, legally represented by the Board, Mr. Peter Albrecht, ibid,

Plaintiff 1),

- Counsel: Patent Attorneys Dipl.-Phys. Haft et al.,
Franziskanerstraße 38, 81669 Munich, -

and

2) Scimed Life Systems Inc., Scimed Place, Maple Grove, N.M. 55311-1566, USA, legally represented by Mr. Michael Berman, 10727 Geneve Lane, Minnetonka, Minnesota 55305, USA,

Plaintiff 2),

- Counsel: Patent Attorneys and Attorneys at Law Bardehle et al., Galileiplatz 1, 81679 Munich, -

versus

Arterial Vascular Engineering, Inc. 3576 Unocal Place, Santa Rosa, CA 95403, USA, legally represented by its President, Scott Solano, ibid,

Defendant,

- Counsel: Patent Attorneys Dipl.-Eng. H, Zimmermann et al., Rosental 7, 80331 Munich, -

relating to the European Patent 0 417 928,

the 4th Senate (Nullity Senate) of the Federal Patent Court at the hearing on 5 September 2000 with the participation of the Presiding Judge Dr. Schwendy, Judges Dipl.-Eng. Klosterhuber, Dipl.-Eng. Haaß, Dipl.-Phys. Dr. Kraus and Mr. Müllner

has held as follows::

The European Patent 0 417 928 is nullified within the scope of claims 1 to 8 for the territory of the Federal Republic of Germany.

The costs of the litigation shall be borne by the defendant.

The judgment is provisionally enforceable for plaintiff 1) on security in the amount of 36,000.00 DM and for plaintiff 2) on security in the amount of 53,000.00 DM.

Findings of fact

The defendant is registered owner of the European Patent 0 417 928 (litigious patent) granted with effect for the Federal Republic of Germany, which had been applied for on 24 August 1990 claiming as priority the U.S. patent application 398180 dated 24 August 2000 *[sic]*. The litigious patent, published in the English language of the proceedings and filed at the German Patent Office under the number 690 29 114, relates to a device and a method for endovascular support. It comprises 9 claims, of which claim 1 is worded as follows in the German translation:

> *[In German, here back-translated to English:]* "1. Endovascular support device which is suitable for an implantation in a coronary or other blood vessel in the human body, comprises a unitary member (10) which is so configured that it has a plurality of upper and lower peaks (12, 14), the unitary member being capable of being compressed onto the outer surface of a catheter in order to be delivered to an affected area of a blood vessel and then expanded by inflation of the catheter in order to maintain the affected area of a blood vessel at a diameter that is larger than if the support device were not implanted, characterized in that the unitary member is of wire-like material and has no joints."

For claims 2 to 8 which refer back directly or indirectly to claim 1, reference is made to the litigious patent specification.

The plaintiff 1) bases its partial nullity action directed against the litigious patent within the scope of claims 1 to 7 on lack of novelty and lack of inventive activity, and cites the following publications in that regard:

(1) US 4,773,665 (K5 or NK2)
(2) US 4,214,587 (K8 or NK4)
(3) EP 0 177 330 A2 (K10 or NK3)
(4) US 4,800,882 (K11)

The plaintiff 2) bases its partial nullity action directed against the litigious patent within the scope of claims 1 to 8 on inadmissible broadening, lack of practicability, and also lack of inventive activity. It cites essentially the same publications.

The plaintiff 1) petitions that

> the European Patent 0 417 928 be nullified within the scope of claims 1 to 8 for the territory of the Federal Republic of Germany.

The defendant petitions that

> the actions be dismissed, alternatively subject to the proviso that the patent be maintained with the version of claim 1 as submitted at the hearing.

It denies the plaintiffs' assertions in all points and considers the litigious patent to be valid, at least in the wording defended as an alternative.

Claim 1 according to the alternative petition contains the following addition joined to the granted claim 1:

> ".....the peaks (12, 14) being rounded with a diameter of curvature greater than the diameter of the wire-like material."

Grounds for the decision

The actions with which the plaintiffs assert the grounds of nullity entailing lack of patentability, inadmissible broadening and inadequate disclosure as provided in Art. II § 6 Para. 1 No. 1 International Patent Convention Law, Art. 138 Para. 1 letters a and c EPC [European Patent Convention] in conjunction with Art. 54 Para. 1, 2 and Art. 56 EPC are fully justified.

1. The litigious patent relates to a device and a method for endovascular support. According to the concurring opinion of all participants, such supports involve an implant called a "stent" in the art. According to the

description in the litigious patent, such devices are used to lessen the risk of restenosis of the affected artery after a percutaneous transluminal coronary angioplasty. Such stents were normally introduced into the blood vessel in the region of the lesion and then expanded in order to keep the passage open. In the case of all the stents in the form of so-called mesh wires *[stet; probably should be "wire meshes" - Tr.]* described in the prior art --e.g., in US 4,733,665, US 4,776,337 or EP 0 177 330--, significant difficulties have been encountered and each has its own percentage of thromboses, restenoses and tissue ingrowths, as well as varying degrees of difficulty in deployment. In the case of some prior-art stents, conformation to the blood vessel shape presents further difficulties. Since additionally their relatively long length makes it difficult to treat curved vessels, and anticoagulants were originally required at least for the first three months after insertion, such stents would have had but little acceptance within the medical community as a practical method for treating chronic restenosis. Thus there has long been a need for a stent which is effective to hold a vessel open, without resulting in significant thrombosis, and which can easily be used in multiples to treat curved blood vessels and varying lengths of lesions.

2. Against this background, the litigious patent specification formulates the problem of providing a stent which substantially eliminate the limitations of the prior art, is capable of being implanted simply and reliably, which does not result in significant thrombosis and which can be selectively sized in accordance with the anatomic configuration dictated by the lesion itself.

3. In accordance with that, claim 1 describes a device having the following features:

    a) Endovascular support device which is suitable for an implantation in a coronary or other blood vessel in the human body;
    b) the support device comprises a unitary member
    b1) the uniform member has a plurality of upper and lower peaks

b2) the unitary member being capable of being compressed onto the outer surface of a catheter in order to be delivered to an affected area of a blood vessel;

b3) the uniform member can be expanded by inflation of the catheter in order to maintain the affected area of a blood vessel at a diameter that is larger than if the support device were not implanted

b4) the unitary member is of wire-like material

b5) the unitary member has no joints.

4. a) The contested claim 1 of the litigious patent is admissible. Its subject matter is disclosed in the original and in the granted documents. The specifically contested feature "and has no joints", which in correct translation into German means "and has no connecting elements" (the translation in the litigious patent specification is incorrect), follows from, e.g., Figure 1 in conjunction with the description at column 5, lines 23 to 28 and lines 43 to 53 (EP 0 417 928 A1) or Figure 1, description at column 5, lines 22 to 24 and lines 39 to 48 (EP 0 417 928 B1). Contrary to the plaintiffs' opinion, the subject matter of claim 1 is also practicable, at least when the description is added. Reference is made here in particular to column 5, lines 39 et seq.

Further comment on that subject and on the novelty of the subject matter of claim 1 (to be affirmed) is unnecessary, since that subject matter is not based on an inventive activity.

In the Senate's opinion, the feature "no joints" or "no connecting elements" should be interpreted such that no connecting struts of any type are disposed between the individual straight segments (16 in Figure 1) of the stent and that the stent consists of an endless material, as can be discerned from column 5, lines 39 to 48 of the litigious patent specification.

Known from (3) is a stent (endovascular support device) which is suitable for an implantation in a coronary or other blood vessel in the human body (page 1), comprises a unitary member (Figure 1) which is so configured that it has a plurality

of upper and lower peaks (13 in Figure 1), the unitary member being capable of being compressed in the interior of a catheter in order to be delivered to an affected area of a blood vessel (page 3 and page 6, 2nd paragraph) and then expanded by ejection from the catheter in order to maintain the affected area of a blood vessel at a diameter that is larger than if the support device were not implanted (page 5, last paragraph). The unitary member is of wire-like material (page 5, middle paragraph, claim 1).

The subject matter of claim 1 differs from that prior art in that in the case of the stent of claim 1 the wire is not connected with a sheath at its ends but rather comprises an endless wire, and in that it is expanded at the deployment site by inflation of a catheter and does not expand by itself to a prescribed diameter after expulsion from the catheter, as is the case for the stent according to (3).

The person of average skill in the art, to whom the present teaching is directed, is a technician concerned with the development and manufacture of prostheses and devices for vascular surgery, especially stents, who obviously has exact knowledge of the relevant materials and their properties and who collaborates with a vascular surgeon in connection with medical problems.

When that person skilled in the art ascertains --or when it is brought to his attention by a surgeon-- that the stent known from (3) which is made from a self-expanding material leads to difficulties in the deployment process because, as the defendant stated, the stent expands nonuniformly when it is expelled or does not assume the required diameter, then he will search for solutions. First of all, he will draw upon the known principle (see, e.g., (4), (1)) according to which stents are expanded at the deployment site, e.g., by means of a balloon, and will investigate that for its suitability. Thus, he will transfer the principle of expanding stents to the required diameter at the deployment site by means of a balloon catheter to the subject matter of (3). That merely means making the known stent from an appropriate material which, for example, is plastically deformable instead of being elastic. His specialized knowledge makes him immediately capable of doing that, and all the more so because for the subject matter of claim 1 of the litigious patent he must also make a specific selection of the material on the basis of his knowledge.

Contrary to the defendant's opinion, the Senate is persuaded that, when necessary, the person skilled in the art is immediately capable of changing over from one of the described stent principles to the other, as is evidenced in particular by the publication Radiology, February 1987, page 482, left column, first paragraph, according to which a balloon expansion was performed additionally after the deployment of a self-expanding stent.

The person skilled in the art is also not presented with any problem at all by the omission of the sheath 11 in the exemplary embodiment of the stent according to (3) and its formation from an endless wire (ring), especially since the generalizing teaching of claim 1 in (3) already speaks of a wire which is bent in a closed zig-zag shape and does not mention any separate connecting element such as a sheath or the like.

Hence, seen in its entirety, the subject matter of claim 1 is not based on an inventive activity.

The interpretation of claim 1 (particularly the term "no joints") by the defendant, which does not want to consider an endless wire included as starting material, would also not change anything here, because, as is already implied in the comments above, that embodiment is not based on an inventive activity.

b) The contested subclaims 2 to 8, for which no independent protection was claimed, share the fate of claim 1. Moreover, the subject matter of claim 2 is known from (3), page 5, middle paragraph. The subject matter of claim 3 relates to an obvious development. Suggestions thereto are provided in (4), especially claim 3 thereof.

The subject matters of claims 4, 5 and 7 relate to practical developments which are directed toward specific applications and hence contain nothing of an inventive nature.

The subject matter of claim 6 differs from the subject matter of publication (3) only through the different principle adopted for expanding the stent at the deployment site. That difference was already commented upon in connection with claim 1, so reference is made thereto.

The subject matter of claim 8 is known from (3). In particular, see Figure 1 and the associated description.

5. Claim 1 in the alternative petition differs from the one in the main petition by the additional feature "the peaks (12, 14) being rounded with a diameter of curvature greater than the diameter of the wire-like material" or, in German translation:
"that the peaks (12, 14) are rounded with a diameter of curvature greater than the diameter of the wire-like material".

That claim is inadmissible. According to the defendant's statements too, the cited feature originates solely from the drawing. Features that are only drawn but are not mentioned in the description and the claims can be considered to have been disclosed in a manner essential to the invention if on the application date the cognizant person skilled in the art would recognize them as belonging to the invention even though they are not mentioned in the description and claims (Schulte, Patent Law, 5th edition, §35, marginal No. 164). But that is not the case here. Here the drawn feature is overwhelmed by the features that are both described and drawn, so that no claim can be directed toward it (see Schulte, loc. cit.). Further comment about this is unnecessary, however, since the cited feature is known from (3) (see page 5, last paragraph and patent claims 4 and 7).

On page 5, last paragraph, the diameter of curvature for the peaks is indicated to be 0.4 cm (or a radius of 0.2 cm) and a figure of 0.046 cm (or 0.018 inch) is cited for the wire diameter. That meets the condition stated in claim 1, and does so even if, as the defendant believes, the dimensional information in (3) should be in "mm" instead of "cm".

Accordingly, the differences compared to the prior art in (3) are the same as in the case of claim 1 in the main petition. The subject matter of this claim 1 are thus

based on the same grounds as those stated in connection with claim 1 in the main petition, and not on any inventive activity.

As regards the subclaims, reference is made to the comments made above in 4.) b).

6. The decision as to costs is based on § 84 Para. 2 of Patent Law in conjunction with § 91 Para. 1 Sentence 1 of the Code of Civil Procedure. The decision as to provisional enforceability is based on § 99 Para. 1 of Patent Law in conjunction with § 709 of the Code of Civil Procedure.

Dr. Schwendy Mr Klosterhuber Mr. Haaß Dr. Kraus

Judge Müllner
is prevented from signing
because of vacation.

Dr. Schwendy

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